SEP 26 2005

stryker

K051369

Canada

510K Summary: Stryker Sorano Wheelchair

Trade Name: Stryker Sorano

Common Name: Manual Wheelchair

Classification Name: Wheelchair, Mechanical 891IOR

Device Sponsor:

Stryker Canada
45 Innovation Drive
Hamilton, ON, Canada
L9H 7L8

Regulatory Class: Class I 21 CFR 890.3850 Mechanical Wheelchair

Contact Person:

Kathryn Ronalds, Senior Regulatory Affairs Representative

Predicate Device:

The Stryker Sorano Wheelchair is substantially equivalent to the Invacare Top End Terminator Titanium Manual Wheelchair (K012167, Aug 1/01).

Intended Use:

The Stryker Sorano Wheelchair is a mechanical wheelchair intended to provide mobility to persons restricted to a seated position.

Device Description:

The Stryker Sorano Wheelchair is a manually operated, user propelled mechanical wheelchair. It is intended to provide mobility to persons restricted to a seated position.

The product consists of a titanium frame (also available in chrome-moly steel), large rear wheels with handrims for propelling the chair, and smaller front pivoting casters for stability. The wheelchair is a lightweight manual chair designed for everyday use, both indoors and outdoors. The wheelchair is a rigid, non-folding type wheelchair.

The Stryker Sorano offers a suspension system made of a fibre glass composite. The two suspension elements are part of the frame construction as they connect the main frame to the rear wheel axle. As it is part of the frame, the suspension is a standard feature.

The Stryker Sorano offers an additional propulsion method to conventional handrims. A lever drive option may be added that provides two forward gear ratios an incorporates a disc braking system. Handrim use is still possible as handrims are standard on all units. The key benefits to the drive system are that it eliminates the need to grip the handrim, provides mechanical advantage and provides an enhanced braking system.

The Stryker Sorano also offers modularity and adjustability features. The seat height, angle, rear seat-to-floor height, and front seat-to-floor height may be adjusted by the end user. The footrest module with caster wheels may be adjusted forward and backward, and the footrest height may be adjusted. The backrest angle and height may also be adjusted. In addition, the footrest module is removable and may be replaced with optional sports or other special purpose footrests. The seat/backrest module and the footrest module may be removed by the user, allowing the entire wheelchair to be packed in a compact space for travel. The optional folding backrest enhances this feature.

Performance Data:

The Stryker Sorano Wheelchair will meet the applicable performance standards specified in Rehabilitation Engineering Socicy of North American (RESNA) Standard ANSI/ RESNA WC/Vol. 1-1998 "Requirements and Test Methods for Wheelchairs."

Substantial Equivalence (SE) Rational:

The Stryker Sorano Wheelchair is equivalent in intended use, safety, and effectiveness to existing devices being marketed by Invacare.

Safety and Effectiveness:

The Stryker Sorano Wheelchair does not raise any new safety and efficacy concerns when compared to a similar device already legally marketed. Therefore, the Stryker Sorano Wheelchair is substantially equivalent to this existing device.

Signed: Kathryn Ronalds Dated: May 20, 2005
Kathryn Ronalds
Senior Regulatory Affairs Representative

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 26 2005

Ms. Sheryl Bagalio
Regulatory and Quality Affairs Supervisor
Stryker Canada
45 Innovation Drive
Hamilton, ON, Canada
L9H 7L8

Re: K051369
Trade/Device Name: Stryker Sorano Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: I
Product Code: IOR
Dated: August 18, 2005
Received: August 19, 2005

Dear Ms. Bagalio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510K Number: TBD

Device Number: Stryker Sorano Wheelchair

Indications for Use: The Stryker Sorano Wheelchair is a mechanical wheelchair intended to provide mobility to persons restricted to a seated position.

Prescription Use _____ AND/OR Over-The-Counter Use ___✓_____
(Part 21 CFR 801.109)

(Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K051369